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IQ/OQ Protocol Installation Qualification/ Operation Qualification

RapidVap® N_2 & N_2/48 Evaporation Systems

Labconco No. – 1058803, Rev. B, ECO L395
Available at **labconco.com**

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with new or relocated Labconco RapidVap N_2 & N_2/48 Systems. RapidVap Vacuum Systems are covered in a separate document, #1058802.

Models: RapidVaps

7910000	*7910001*	*7910010*	*7910011*
7910012	*7910013*	*7910014*	*7910015*

It is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning the site for the piece of equipment and therefore is of value prior to receipt of product.

The use of this document does not replace the need for the RapidVap User's Manual (#7490100). Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or down-loaded from their website, www.labconco.com

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the evaporator is installed and operating properly. This document can assist in that validation. This document cannot however anticipate every application or unique situation encountered with the installation and operation. It is therefore essential that users, lab managers and safety officers work together to broaden the scope of this document through careful forethought.

End-User Employer – The employer is responsible for supporting the validation through adequate resources and training. The organization shall also ensure the validation process has been fully carried out prior to applying the RapidVap. Records should be stored in a safe, easily retrievable location. The location of the equipment and required validation should be included in the company's quality system.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test each RapidVap prior to shipment. The manufacturer must retain these records. Labconco's staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for the actual installation or validation processes.

Performance Qualification

Once the evaporator has been checked for proper installation and basic operation, it may be decided to validate its performance. Labconco cannot recommend specific procedures to do this. The performance validation should be designed to meet the specifications and accuracy required of the application.

In general this requires establishing acceptance criteria, making several runs and testing the results with calibrated equipment and qualified personnel.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	**Site Planning**			
1a	Space Requirements	Refer to Appendix B in User's Manual for dimensions of the model(s) you have chosen. Has adequate counter space been provided for placement of the equipment?	Y	N
1b	Electrical Service	Refer to the User's Manual for a list of model numbers and their corresponding electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage?	Y	N
		230V models are shipped with a power cord plug. (It may require replacement.) Is one available to match the service outlet at the installation site?	Y N/A	N
1c	Exhaust Requirements	Refer to chapter 2 of the User's Manual 74790100. Have accommodations been made to vent the RapidVap safely? (6-ft of 2" ID hose is provided.)	Y	N
1d	Nitrogen Supply	Have accommodations been made to have a supply of dry nitrogen? Tanks do not have enough capacity, a nitrogen generator or house-plumbed nitrogen. See Appendix C of the User's Manual for an estimate of nitrogen consumption.	Y	N

	N_2 Supply Regulator	Gas supply MUST be regulated to less than 20 psi, (5-15 psi is recommended). Has a regulator equipped with gauge to accommodate a ¼-inch ID line been procured for this installation? (Nitrogen supply hose is 72" long.)	Y	N
2	**Prior to Operation**			
2a	Damage Claims	Have the delivered products been inspected for any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete. If damaged, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	Nitrogen Connections	Has the nitrogen connection been made to the RapidVap?	Y	N
2c	Glassware Block	Does the sample block match the size of tubes you wish to use in this evaporator?	Y	N
		Has the block been placed into the RapidVap's chamber and secured with the three nuts?	Y	N
2d	Handling Solvents	Has the Safety Officer, or equivalent, reviewed the safe handling, venting and disposal of solvents evaporated?	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	**RapidVap**			
1a	Preheat	Activate the Preheat feature. With the lid closed, does the chamber heat up?	Y	N
1b	Heat and Run	Select any program and set a higher than ambient temperature and set the Run Time to one minute to check operation. Did the chamber oscillate and heat when the lid is closed?	Y	N
1c	Run Timer	Did the alarm sound and oscillation stop after one minute?	Y	N
1d	Temperature Control	Set the speed to zero. Attach a thermocouple wire on the top of the sample block next to the retaining nut at the 7:00 position. With nitrogen OFF, close the lid. With the Temp. Control set at 45 °C, press Run: RapidVap Display Temperature: _____ (Display should be between 44 and 46 °C) Reference Device Temperature: _____ (Device should read between 42 and 48 °C) With the Temp. Control set at 95 °C: RapidVap Display Temperature: _____ (Display should be between 94 and 96 °C) Reference Device Temperature: _____ (Device should read between 91 and 99 °C) Ref. Device ID _____	Y	N
1e	Interrupt Cycle	Repeat the one-minute cycle, except this time, press the STOP button to interrupt the cycle. Did the oscillation stop? When Run is pressed, did the cycle resume?	Y	N
1f	Nitrogen Flow	Is the nitrogen flow controlled through the valves? To visually observe flow, equally fill each vial with water to approximatly .75-inch from the top. Heat is OFF, speed is set at 0,N_2 ON, press Run. Follow instructions in the User's Manual to turn valves ON and OFF. Do the valves appear to operating properly?	Y	N

1g	Nozzle Flow Rate (A flow meter is required to complete this step.)	Choose to visually check or measure that flow through each nozzle is adequate. To visually inspect flow, use the water-filled vials from the above step. Observe the surface of the water in each vial. Does the depression made by the N_2 appear uniform in size and location? A measurement of flow rate can be made using a (0-10) SCFH flow meter attached to a 1/8" ID plastic tube. Place the end of the tube over each nozzle. In order for the nitrogen to operate with the lid open, place a magnet over the lid switch in the front left corner of the lid gasket. Speed is set at 0, Heat OFF, N_2 ON all positions, N_2 pressure = 20 psi, press Run. Are all nozzles measured within 2.5 SCFH?	Y	N
1h	Vortex Speed (Optional; a calibrated tachometer is required to complete this step.)	Place a piece of aluminum tape on the top of the sample block. Set the following speeds and measure with a calibrated optical tachometer. Does the RapidVap operate at RPM's in the allowable tolerance? Set Pt. Display Allowable Tach. Allowable 0 _____ 0 _____ 0 24% _____ 22/26 _____ 105/135 100% _____ 98/102 _____ 480/520 Tachometer ID _____	Y N/A	N
1i	RS-232 Optional Accessory Communication Port	Refer to the User's Manual 7490100 for instructions on connections and operation of the RS-232 communications with the RapidVap. To test the connections and output, use cable #7484800. Send each of the RS-232 commands listed in the User's Manual and observe the results. Did the RapidVap respond correctly to the commands?	Y N/A	N
2	**Personnel Training**			
2a	User Training	Have personnel to use the RapidVap been adequately trained? Are personnel familiar with: Volume limits of samples in vials; Loading of vials in heated block; Safe handling of solvents and vapors; Programming time and temp. parameters; Cleaning and maintenance of the RapidVap?	Y	N

C. Summary

Labconco RapidVap N_2 & N_2/48 System IQ/OQ Document 1058803 Revision B

Equipment Location _____

RapidVap Ser. No. _____ Model No._____

User Protocol _____ Revision (or Date published) _____

Contact (print name):_____
Title: _____

Review the "Response" columns for answers of "NO." Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for "Corrective Actions." Once acceptable results are obtained, the deficiency is "accepted" by initialing the Corrective Action.

Step	Deficiency followed by Corrective Action	Initial